IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MIGHTY OAK MEDICAL, INC., Plaintiff, v. MEDACTA INTERNATIONAL SA and MEDACTA USA, INC., Defendants.	C.A. No. 1:22-cv-01625-GBW

DEFENDANTS' BRIEF IN SUPPORT OF ITS MOTION TO DISMISS PLAINTIFF'S COMPLAINT (D.I. 1) FOR FAILURE TO STATE A CLAIM

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I. NATURE AND STAGE OF THE PROCEEDINGS

On December 22, 2022, Plaintiff Mighty Oak Medical, Inc. ("Mighty Oak") filed its Complaint (D.I. 1) against Defendants Medacta International SA and Medacta USA, Inc. ("Medacta") for alleged infringement of U.S. Patent Nos. 8,758,357 ("the '357 Patent"), 8,870,889 ("the '889 Patent"), 9,198,678 ("the '678 Patent"), 9,642,633 ("the '633 Patent"), and 9,987,024 ("the '024 Patent") (collectively, the "Asserted Patents").

Count III accuses Medacta of infringing claim 11 of the '678 Patent, *see* D.I. 1 ¶¶ 72-73; D.I. 1-15 at 7, but Mighty Oak fails to allege facts plausibly supporting this accusation. Medacta therefore moves to dismiss Count III of the Complaint under Federal Rule of Civil Procedure 12(b)(6), and contemporaneously answers the remaining Counts. This case has not otherwise progressed.

II. SUMMARY OF THE ARGUMENT

1. Medacta moves to dismiss Count III of the Complaint pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted. Although Mighty Oak accuses Medacta's products of infringing claim 11 of the '678 Patent, the Complaint is devoid of any facts plausibly showing that Medacta's MySpine Standard, MySpine Low Profile, MySpine MC, and MySpine S2AI (the "Accused Products") contain each and every claim limitation. *See* D.I. 1 ¶¶ 72-73; D.I. 1-15 at 7.

2. To state a claim for infringement of claim 11 of the '678 Patent, Mighty Oak must plead sufficient facts to render it plausible that the Accused Products have, *inter alia*, an "arcuate bridge configured to be selectively engaged with the first and second patient-specific elements at a location beyond the patient's anatomy." The Complaint (including the claim chart attached as Exhibit 15), however, merely identifies features that allegedly constitute the recited "bridge" and "first and second patient-specific elements." *See* D.I. 1; D.I. 1-15. Mighty Oak never identifies

any purported "selective[] engagement" between the "bridge" and the "first and second patient-specific elements." *See id.*

3. Further, Exhibit 15 and the evidence cited by the Complaint show that any engagement between the features Mighty Oak accuses is not "selective[]." The evidence accompanying the Complaint shows that the accused "bridge" and "first and second patient-specific elements" are part of unitary constructions, and thus permanently or fixedly connected to each other. Thus, there is no plausible factual basis to support a claim for infringement of claim 11 of the '678 Patent.

4. This deficiency is evident from the plain language of claim 11 and does not reflect a claim construction dispute. Thus, given this incurable factual deficiency, Count III should be dismissed with prejudice.

III. STATEMENT OF FACTS

Mighty Oak's Complaint accuses Medacta of infringing the Asserted Patents, which are generally directed to patient-specific surgical guides for spinal surgery. *See* D.I. 1 ¶¶ 14-18. Count III asserts that the Accused Products infringe claim 11 of the '678 Patent. *See* D.I. 1 ¶¶ 72-73; D.I. 1-15 at 7.

Claim 11 is directed to an "orthopedic device for use in a minimally invasive surgical procedure," and recites:

> 11. An orthopedic device for use in a minimally invasive surgical procedure, comprising:
>
> **a first patient-specific element** configured to at least one patient-specific surface determined from a patient's anatomy and which anatomically conforms to at least a first subcutaneous anatomic feature of a specific patient;
>
> **a second patient-specific element** configured to at least one second patient-specific surface determined from a patient's anatomy and which anatomically conforms to at least a second subcutaneous anatomic feature of a specific patient; and

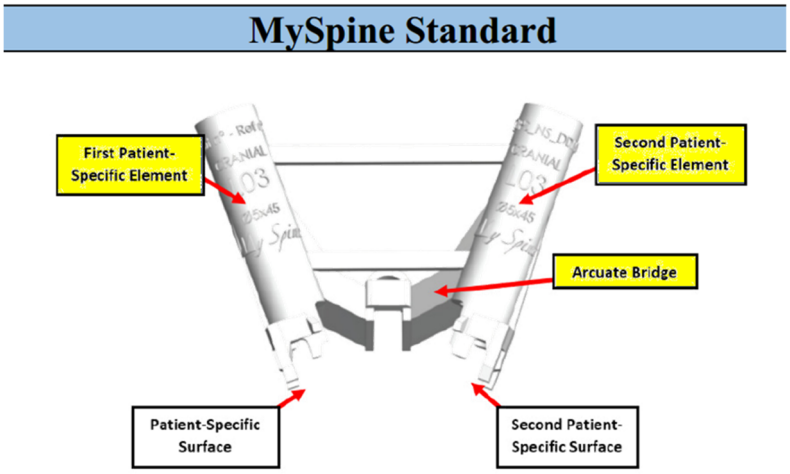
> **an arcuate bridge** coupling the first and second patient-specific elements, the arcuate bridge configured to be ***selectively engaged*** with the first and second patient-specific elements at a location beyond the patient's anatomy.

D.I. 1-3 at cl. 11.[1]

As emphasized above, claim 11 requires the claimed device to have certain physical elements, including (1) a "first patient-specific element"; (2) a "second patient-specific element"; and (3) a "bridge." And the claim further requires a particular configuration for these features—the "arcuate bridge" must be "coupling the first and second patient-specific elements." *Id.* And it further must be "configured to be ***selectively engaged*** with the first and second patient-specific elements at a location beyond the patient's anatomy." *Id.*

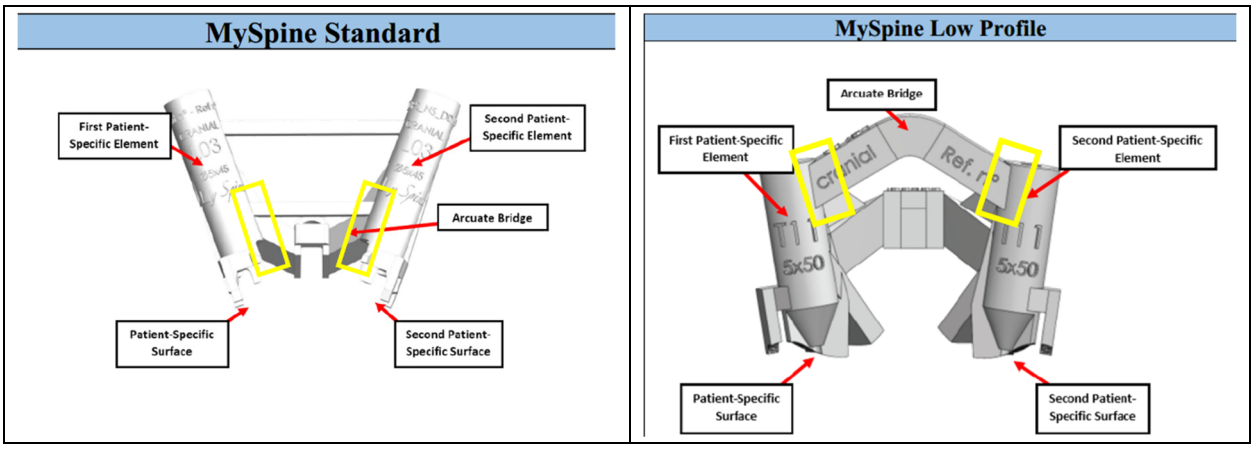
The Complaint and Exhibit 15 fail to identify any "bridge" that is "***selectively engaged*** with the first and second patient-specific elements." *See* D.I. 1; D.I. 1-15. The Complaint relies exclusively upon Exhibit 15 to identify aspects of the Accused Products that allegedly meet the limitations of claim 11. *See* D.I. 1 ¶¶ 71-72 (otherwise offering conclusory allegations). Exhibit 15 attempts to show how the Accused Products meet the "selectively engaged" limitation by referencing "annotated figures" previously provided in that exhibit. D.I. 1-15 at 7. But these annotations only identify the alleged "arcuate bridge," "first patient-specific element," and "second patient-specific element" (highlighted below in yellow)—they nowhere identify any purported "selective[] engagement" between those features:

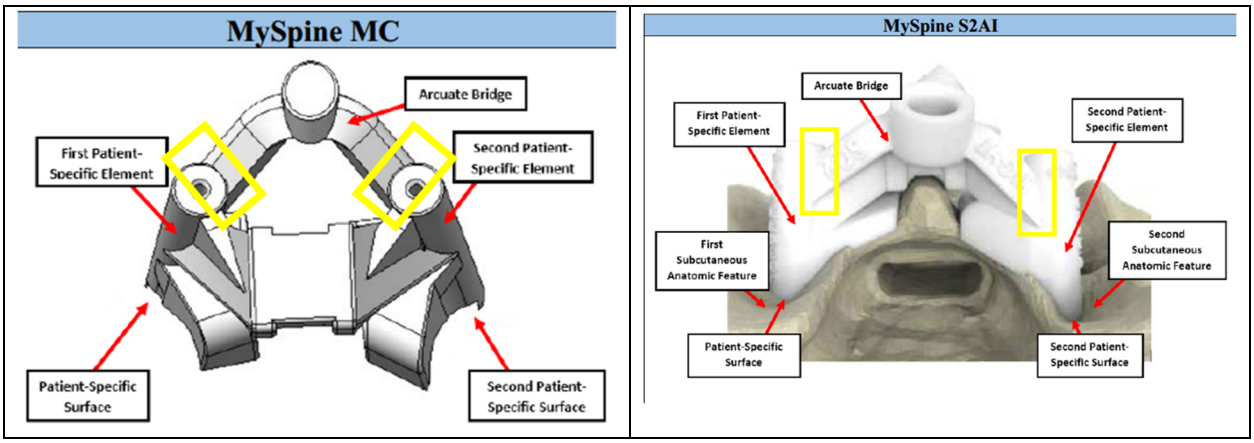
[1] Emphasis is added throughout unless otherwise noted.



Id. at 3; *see also id.* at 3-6 (providing annotated figures for MySpine Standard, MySpine Low Profile, MySpine MC, and MySpine S2AI that likewise lack any reference to "selective[] engagement").

Indeed, the features accused by Mighty Oak of being the "bridge" and "first and second patient-specific elements" are parts of a unitary structure, and thus permanently or fixedly connected to each other. This fixed connection is evident from the images Mighty Oak provides throughout Exhibit 15, as highlighted below in yellow:





Id. Additional examples of certain MySpine Standard, MySpine Low Profile, MySpine MC products showing this fixed connection can be found throughout the MySpine Surgical Techniques cited by Mighty Oak. *See generally* Ex. A; *see also* D.I. 1-15 at 2 (citing and providing hyperlink to same). And additional examples of certain accused MySpine S2AI products showing this fixed connection can be found throughout the MySpine S2-Alar/Alar-Iliac Surgical Technique cited by Mighty Oak. *See generally* Ex. B; *see also* D.I. 1-15 at 2 (citing and providing hyperlink to same).

* * *

Before bringing this motion, Medacta first sought to resolve this issue without Court intervention. On March 14, 2023, counsel for Medacta contacted counsel for Mighty Oak to explain the factually deficient allegations regarding the '678 Patent and request dismissal of Count III. *See* Ex. C (explaining that the "selectively engaged" "limitation cannot be met by the accused products, which comprise a singular integrated piece with the alleged 'bridge' directly fixed to the alleged 'first and second patient-specific elements'"). Counsel for Mighty Oak responded on March 24, expressing their disagreement and their belief that Medacta's arguments "indicate[s] a claim construction dispute." *See* Ex. D. This motion ensued.

IV. LEGAL STANDARD

A complaint must contain "sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Plaintiff must "allege sufficient facts 'to raise a reasonable expectation that discovery will reveal evidence' that supports the plaintiff's claim." *Id.* (quoting *Twombly*, 550 U.S. at 556). While a court must accept all "well-pleaded facts" as true, that requirement does not apply to legal conclusions. *Iqbal*, 556 U.S. at 678-79.

To plead patent infringement, the complaint must put the defendant "on notice of what activity . . . is being accused of infringement." *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1350 (Fed. Cir. 2018) (quoting *K-Tech Telecomms., Inc. v. Time Warner Cable, Inc.*, 714 F.3d 1277, 1284 (Fed. Cir. 2013)). Patent infringement requires showing that the accused device contains every limitation in the asserted claims." *Mas–Hamilton Grp. v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed. Cir. 1998) (citation omitted). If even one "claim limitation is totally missing from the accused device," then "[t]here can be no [direct] infringement as a matter of law." *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538-39 (Fed. Cir. 1991); *see also Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2116-2117 (2014) (explaining that "there can be no indirect infringement without direct infringement" and any allegation of indirect infringement "must be predicated on [an underlying] direct infringement").

Thus, at the pleading stage, "a plaintiff must generally do more than assert that the product infringes the claim; it must show *how* the defendant plausibly infringes by alleging some facts connecting the allegedly infringing product to the claim elements." *Bos. Sci. Corp. v. Nevro Corp.*, No. 18-cv-0644-CFC, 2019 WL 6310225, at *3 (D. Del. Nov. 25, 2019) (citation omitted) (italics in original); *see also Metricolor LLC v. L'Oreal S.A.*, 791 F. App'x 183 (Fed. Cir. 2019) (patentee failed to adequately plead infringement where its factual allegations failed to show accused product

met a certain claim limitation, an air-tight seal); *Swirlate IP LLC v. Keep Truckin, Inc.*, No. 20-cv-1283-CFC, 2021 WL 3187571, at *2 (D. Del. July 28, 2021) (dismissing infringement claim that merely identified accused product and generally cited accused infringer's website). When there are no relevant facts in dispute and, in the context of the case, it is clear as a matter of law that the defendant cannot infringe, the complaint should be dismissed. *Ottah v. Fiat Chrysler*, 884 F.3d 1135, 1141-42 (Fed. Cir. 2018) (affirming dismissal when the claims required a "book holder" that was not present in defendants' products).

V. ARGUMENT

Mighty Oak's infringement allegations regarding claim 11 of the '678 Patent are deficient as a matter of law. *First*, the Complaint (including Exhibit 15 thereto) fails to identify "how" the Accused Products embody the claimed configuration of an "arcuate bridge configured to be ***selectively engaged*** with the first and second patient-specific elements at a location beyond the patient's anatomy." The factual material cited by Mighty Oak shows that the accused "bridge" does not "selectively" engage the accused "first" and "second patient-specific elements," and that these features instead form a unitary structure with fixed engagement.

Second, this deficiency does not arise from a claim construction dispute, but from the plain language of claim 11. Thus, the Court should grant Medacta's motion and dismiss Count III.

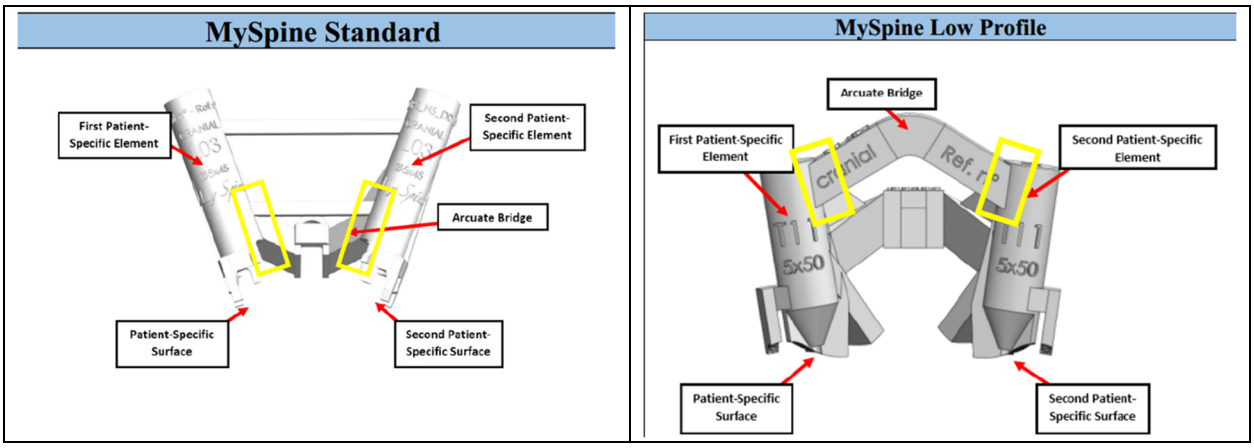
A. Mighty Oak Fails to Identify Any Selective Engagement in the Accused Products

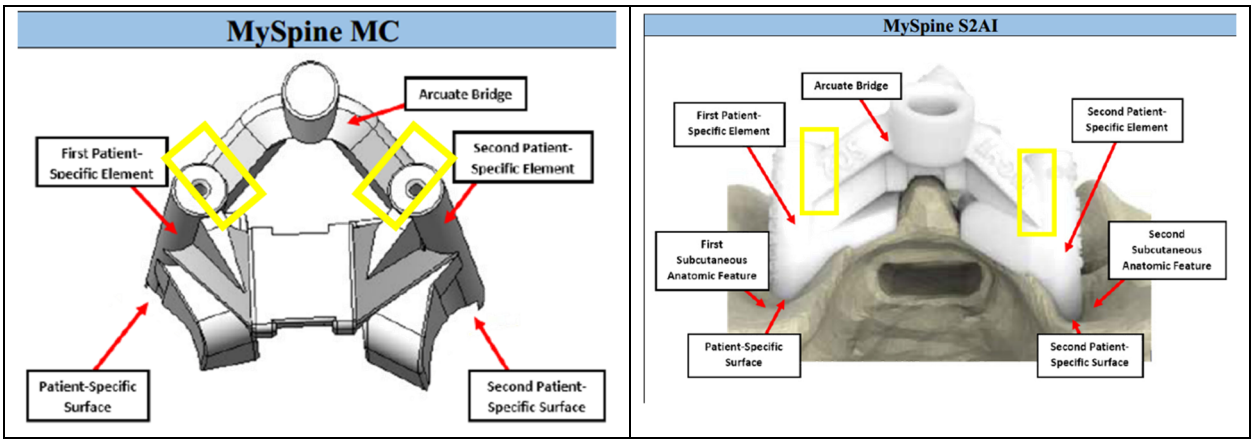
Count III should be dismissed because the Complaint fails to identify any purported "bridge" that is "configured to be ***selectively engaged*** with the first and second patient-specific elements at a location beyond the patient's anatomy." *See Bos. Sci. Corp.*, 2019 WL 6310225, at *3.

As discussed, the main pleading (D.I. 1) offers only conclusory allegations that "Medacta's '678 Accused Products practice all of the limitations of claim 11 of the '678 patent." *See, e.g.*, D.I. 1 ¶¶ 72-73. It nowhere identifies how any limitation—such as a "bridge . . . ***selectively engaged*** with the first and second patient-specific elements"—is allegedly practiced by any Accused Product, and instead references the claim chart attached as Exhibit 15. *Id.*

Exhibit 15, however, fails to address all required elements of independent claim 15, as Mighty Oak must. *See Metricolor LLC*, 791 F. App'x 183 at 188. Exhibit 15 generally alleges that "***[a]s shown in the annotated figures above,*** Medacta's '678 Accused Products include an arcuate bridge coupling the first and second patient-specific elements, the arcuate bridge configured to be ***selectively engaged*** with the first and second patient-specific elements at a location beyond the patient's anatomy. *See* the annotated figures and evidence cited ***above***." D.I. 1-15 at 7. Yet, tellingly, none of these figures provide (via annotation or otherwise) any identification or evidence of an arcuate bridge "selectively engaged" with first and second patient-specific elements.

As discussed, the annotated figures instead illustrate the accused "bridge" being permanently or fixedly (***but not "selectively"***) engaged with the accused first and second patient-specific elements, thereby forming a singular integral construction.





D.I. 1-15 at 3-7; *see also supra* Section III (reproducing exemplary figures from).

These deficient allegations cannot be cured through the Complaint merely "pointing to websites that provide general information" about the Accused Products. *Swirlate IP LLC*, 2021 WL 3187571, at *2; D.I. 1 ¶ 72; D.I. 1-15. Indeed, even if such generalized accusations were legally permissible, they would fail here because the cited evidence merely illustrates the same unitary constructions shown in Exhibit 15, and do not evidence any "selective[] engagement" between the accused features. *See generally* Ex. A; Ex. B.[2]

Any reasonable inquiry into Medacta's Accused Products thus fails to provide plausible facts that could support Mighty Oak's conclusory allegations regarding the "selectively engaged" limitation and "[t]here can be no [direct] infringement as a matter of law." *London*, 946 F.2d at 1538-39 (citation omitted).

[2] Medacta confirms that the Accused Products continue to have unitary constructions with regard to the relevant accused features, even in current iterations.

B. No Construction Is Required to Resolve Medacta's Motion to Dismiss

As noted above, before bringing this motion, Medacta first raised this deficiency to Mighty Oak and requested that it dismiss Count III. Mighty Oak refused, and alleged that Medacta's arguments indicated a claim construction dispute between the parties regarding the correct meaning of the term "selectively engaged." This is incorrect.

First, in suggesting that "selectively engaged" encompasses unitary devices with fixed connections between the relevant features, Mighty Oak effectively takes the position that claim 11 of the '678 Patent merely requires the "bridge" and "first and second patient-specific elements" to be coupled together. This flatly contradicts the plain claim language, which makes clear that ***more*** than mere "coupling" of the "arcuate bridge," and "first and second patient-specific elements" is required to practice claim 11. The "selectively engaged" limitation is part of a larger phrase, and preceded by a separate requirement that the claimed device comprise "an arcuate bridge ***coupling*** the first and second patient-specific elements":

> an arcuate bridge ***coupling*** the first and second patient-specific elements, the arcuate bridge configured to be ***selectively engaged*** with the first and second patient-specific elements at a location beyond the patient's anatomy

'678 Patent, cl. 11.

In other words, the "acuate bridge" must be both (1) "***coupling*** the first and second patient-specific elements"; and (2) "configured to be ***selectively engaged*** with the first and second patient-specific elements at a location beyond the patient's anatomy." As such, the "selectively engaged" language imposes a separate, further limitation on how the coupled "arcuate bridge" and "first and second patient-specific elements" must be configured in the device. No construction is required to see that Mighty Oak has altogether failed to address this limitation and identify any configuration on the Accused Products that could reasonably reflect a "selectively engaged" configuration.

Second, Mighty Oak cannot reasonably contend that the Accused Products' fixed engagement reflects a "selective" engagement, and tellingly did not identify any construction of "selectively engaged" that would encompass such devices in responding to Medacta's request to dismiss Count III. *See generally* Ex. D. "Selectively" is a "commonly understood word" with a "widely accepted meaning"—a meaning that reflects optional choice. *Phillips v. AWH Corp.*, 414 F.3d 1303, 1314 (Fed. Cir. 2005) ("[O]rdinary meaning of claim language as understood by a [POSA] may be readily apparent even to lay judges . . . .").[3] Thus, there is no ambiguity here to construe. "Selectively engaged" requires that the engagement be optional, *i.e.*, that the device permit one to "select" whether or not to engage the "arcuate bridge" and "first and second patient-specific elements."

But even if the claims were not clear on their face, the specification resolves all doubts. Figures 69-73 show exactly such a configuration: a "coupling device 710" (bridge) that is "selectively engaged" with two "retractor[s] 692" (patient specific elements):

[3] This has been recognized by numerous courts. *See, e.g.*, *Netlist, Inc. v. Diablo Techs., Inc.*, 701 F. App'x 1001, 1002 (Fed. Cir. 2017) (finding that "selectively electrically coupling" refers to coupling or decoupling specific data lines); *see also Rotatable Techs. LLC v. Motorola Mobility LLC*, 567 F. App'x 941 (Fed. Cir. 2014) (agreeing that the ordinary meaning of the term "select" means "chosen" in preference to another or others); *National Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195 (Fed. Cir. 1999) (plain meaning of term "select" required that something be "chosen" and not just a preference); *Kraft Foods Group Brands LLC v. TC Heartland, LLC*, C.A. No. 14-028-LPS, 2016 WL 873435, *7-*8 (D. Del. 2016); *Hand Held Prods., Inc. v. Amazon.com*, Civil Action No. 12-768-RGA-MPT, 2014 WL 5779416, *1 (D. Del. 2014); *Sudden Valley Supply, LLC v. Ziegmann*, No. 4:13-CV-00053–JCH, 2014 WL 902875, *12-*14 (E.D. Mo. 2014) (finding "selectively" construed as to "choose to engage the restraint."). The specification also repeatedly applies this meaning to various components. *See, e.g.*, '678 Patent at 17:25-31 (describing a "tube retractor that is selectively removeable from [a] cylindrical body"); *id.* at 19:21-25 (describing "spikes or teeth" that "may further be selectively inserted onto one or more of the patient contacting surfaces as desired"); *id.* at 20:35-39 ("describing that "clamps 272 may be secured" by "a selectively releasable tightening mechanism"); *id.* at 20:59-62 (describing a guide with "one or more portions that . . . may selectively be cut-out or broken off"); *id.* at 32:11-18 (discussing a "selectively removable clip").

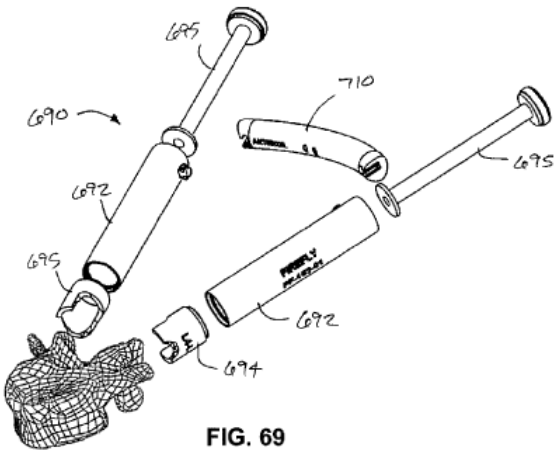


FIG. 69

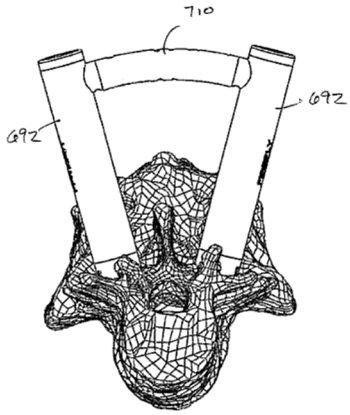


FIG. 72

The ’678 Patent further explains how selective engagement between these features occurs. An “attachment joint” of each “retractor 692” interacts with “a slot or groove” on the “coupling device 710” that allows them to be “joined” or “mated”:

> “***Retractor 692*** may also comprise an ***attachment joint*** located preferably along the outer wall of the generally cylindrical body of retractor 692 for ***receiving a coupling device 710.***
>
> Coupling device 710 preferably has a ***slot or groove*** on each end for receiving one or more attachment joints. In one embodiment, the attachment joint and slot or groove of a particular coupling device 710 are complementary and ***create a secure connection when joined***. In certain embodiments, the connection between attachment joint and slot or groove of coupling device 710 is such that a ***desired*** angle or direction of coupling device is achieved ***once the joint and slot or groove are mated*** (as seen best in FIG. 72). In one embodiment, the connection is ***a locking connection***. In another embodiment, the connection is ***a snap fit connection***. In another embodiment, ***the connection is a frictional engagement*** between the joint and the slot or groove.”

’678 Patent, 34:9-36.

Here, the accused “bridge” and “patient specific elements” of the Accused Products are integrally formed—they do not permit selective mating or joining with each other, as claimed by the ’678 Patent. They lack any indication of any decoupling capability. As an example, an Accused MySpine Low Profile Product is shown below side by side with Fig. 69 of the ’678 Patent.

The accused "bridge" ***does not*** and ***cannot*** "selectively" engage the accused "first" and "second patient-specific elements." Rather, as is clearly shown, it is integrally and singularly formed with the accused "patient-specific elements":

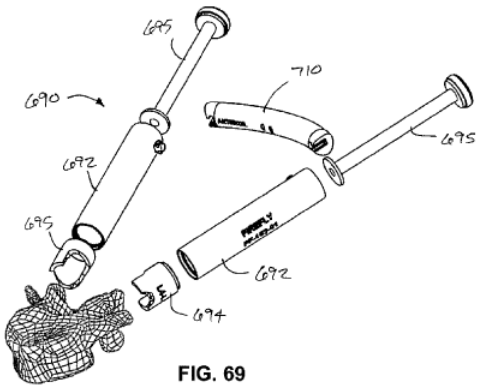
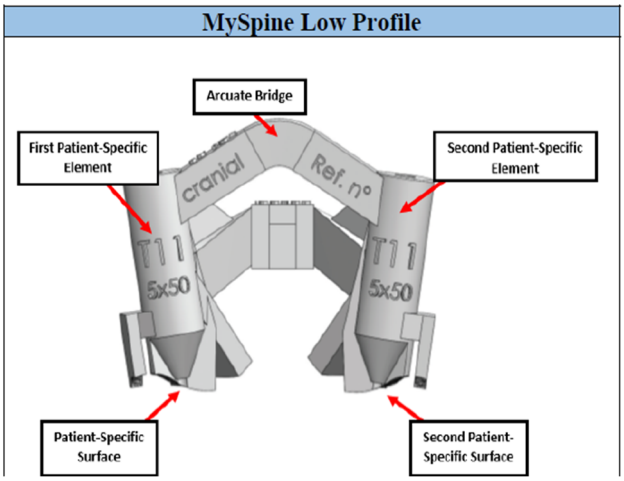


FIG. 69



Compare '678 Patent, Fig. 69, *with* D.I. 1-15 at 4.

Accordingly, there is no factual basis to allege that the Accused Products directly infringe claim 11 of the '678 Patent. And because Mighty Oak fails to state a plausible claim for direct infringement, it likewise fails to state a plausible claim for indirect infringement. *Limelight*, 134 S. Ct. at 2117.

C. The Court Should Dismiss Count III with Prejudice

A court may refuse to grant leave amend a complaint where the proposed amendment would be futile. *Traxcell Techs., LLC v. Sprint Commc'ns Co. LP*, 15 F.4th 1121, 1133-34 (Fed. Cir. 2021); *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000) (citation omitted); *Lorensz v. CSX Corp.*, 1 F.3d 1406, 1414 (3d Cir. 1993) (citation omitted). Amendment is futile where the proposed amended complaint would still fail to state a claim upon which relief could be granted. *In re Burlington Coat Factory Secs. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997) (citation omitted).

Here, because the Accused Products have unitary constitutions without the claimed

"selective" engagement, the factual deficiencies in Might Oak's attempt to state a claim cannot be cured by re-pleading. *See also Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328, 1333, 56 U.S.P.Q.2d 1208 (Fed. Cir. 2000) (affirming denial of leave to amend the complaint after summary judgment of no infringement because "futility of the proposed amendment is an adequate reason to deny leave to amend"); *see also Fields v. Colgate Palmolive Co.*, Civil Action No. 10-365 (PGS), 2010 WL 5252537, at *5 (D.N.J. Dec. 15, 2010) (denying as futile the proposed amended complaint). Thus, the Court should dismiss Count III with prejudice.

VI. CONCLUSION

The Court should dismiss Count III of Mighty Oak's Complaint with prejudice pursuant to Rule 12(b)(6) for failure to plead facts sufficient to state a claim on which relief can be granted.

Dated: April 10, 2023

Respectfully submitted,

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